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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/881,322	06/14/2001	Frank Robert Busch	PC10734A US	7157

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EXAMINER
HUI, SAN MING R

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 01/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application No. 09/881,322	Applicant(s) BUSCH ET AL.	
	Examiner San-ming Hui	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 September 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17 and 30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17 and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4-5* .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

Note: IDS Paper No. 2-3 are copies of Paper No. 4

DETAILED ACTION

Applicant's election with traverse of the invention of Group I, claims 1-17, in Paper No. 7 is acknowledged. The traversal is on the ground(s) that group I and III are overlapped with each other since claim 30 is employing a secondary agent to treat systemic lupus erythematosus. This is found persuasive and the examiner will combine claim 30 with claims 1-17 as one group.

The requirement is still deemed proper and is therefore made FINAL.

The cancellation of claims 18-29 and 31-61 in amendments filed September 10, 2002 is acknowledged.

Applicant's election of the specie of claim 10 in Paper No. 7 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-17 and 30 are pending.

Claims 8, 9, and 11-13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7.

The claims have been examined herein to the extent they read on the elected invention and species.

Claim R jections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the compounds recited in claims 6-17, does not reasonably provide enablement for other growth hormone secretagogue (GHS) compounds. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In the instant case, the specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence of absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art

7) the predictability of the art, and

8) the breadth of the claims.

Applicant fails to set forth the criteria that define a "growth hormone secretagogue ". Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these compounds without undue experimentation. In the instant case, only a limited number of "growth hormone secretagogue" examples are set forth, thereby failing to provide sufficient working examples. It is noted that these examples are neither exhaustive, nor define the class of compounds required. The structural differences among the compounds are great. The only common properties among these compounds are their function as growth hormone secretagogue. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The instant claims read on **all** "growth hormone secretagogue", necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

Claim 14 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant specification, there is no description as to what an "analog of growth hormone releasing factor" is. Applicant fails to set forth the criteria that define an " analog of growth hormone releasing factor ". Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these compounds without undue experimentation. In the instant case, no

examples of "analog of growth hormone releasing factor" is set forth, thereby failing to provide sufficient working examples. The structural differences among the compounds are great. The only common properties among these compounds may be they function as growth hormone releasing factor. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The instant claims read on **all** " analog of growth hormone releasing factor ", necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The expression "growth hormone secretagogue" in claim 1 renders the claims indefinite as to what growth hormone secretagogue compounds are encompassed by the claims. It is not clear to one of ordinary skill in the art what compounds would be considered as growth hormone secretagogue and what is not without further define the structure.

The expression "an analog of growth hormone releasing factor" in claim 14 renders the claim indefinite as to what compounds encompassed by the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-7, 10, 14-17, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carpino'369 (WO97/24369 from the IDS filed July 10, 2002) and Carpino'306 (US Patent 6,107,306) in view of Hahn (Chapter 284: "Systemic Lupus Erythematosus" in Harrison's Principles of Internal Medicine, 13th ed., 1994, page 1643-1648).

Carpino'369 teaches the elected compound as the preferred growth hormone secretagogues (See the abstract and claim 90). Carpino'369 also teaches the compound can be orally administered (See page 31, line 10). Carpino'369 also teaches the compound is known to be useful to improve muscle strength and mobility as well as renal homeostasis (See page 31, line 3-4). Carpino'369 teaches the elected compound

can be used with other GHS, such as GHR-6, and hexarelin, together in treating the disorders (See particularly the abstract).

Carpino'306 also teaches the same genus of compounds as Carpino'369 and those compounds are useful in treating, in addition to the above mentioned conditions, osteoporosis, improving bone remodeling, promoting cartilage formation, and treating peripheral neuropathy (See col. 27, line 16 – 21).

The references do not expressly teach the elected compound be useful in treating systemic lupus erythematosus (SLE). The references do not teach the employment of a secondary agent such as glucocorticoid, antimalarial agent, with the elected compound in the treatment of SLE.

Hahn teaches the clinical manifestation of SLE can be varied such as arthralgias, necrosis of bone, bone deformities, and peripheral neuropathy (See page 1645, Table 284-2). Hahn also teaches the antimalarial agent, quinacrine, and glucocordicoids such as prednisone, methylprednisolone, and prednisolone are useful in treating SLE (See page 1647, col. 2).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the elected compound to treat SLE. It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a secondary agent such as glucocorticoid, antimalarial agent, with the elected compound in the treatment of SLE.

One of ordinary skill in the art would have been motivated to employ the elected compound to treat SLE because the elected compound is useful to treat the clinical

manifestation of SLE such as peripheral neuropathy and renal involvement. One of ordinary skill in the art would have been motivated to employ a secondary agent such as glucocorticoid, antimalarial agent, with the elected compound in the treatment of SLE because antimalarial agent such as quinacrine and glucocorticoids such as prednisone methylprednisolone, and prednisolone are known to be useful to treat SLE. Combining and employing two or more agents which are known to be useful to treat SLE individually into a single composition and method useful for the very same purpose is prima facie obvious. See *In re Kerkhoven* 205 USPQ 1069.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (703) 305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui
January 25, 2003

SREENI PADMANABHAN
PRIMARY EXAMINER

1/25/03